Publicly Available Assessment Report for a
Veterinary Medicinal Product

Dugmectin 18.7 mg/g Oral Paste for Horses

"This product was originally authorised under an EU procedure prior to 1st January 2021 where the UK participated as a Concerned Member State. Therefore, the contents of this Public Assessment Report are not owned by the Veterinary Medicines Directorate. Please contact the original Reference Member State for any queries in relation to this report."

PRODUCT SUMMARY

EU Procedure number	IE/V/0205/001/MR
Name, strength and pharmaceutical form	Dugmectin 18.7 mg/g Oral Paste for Horses
Active substance(s)	Ivermectin
Applicant	ECO Animal Health Europe Limited 6th Floor South Bank House Barrow Street Dublin 4 D04 TR29 Ireland
Legal basis of application	Informed consent application in accordance with Article 13c of Directive 2001/82/EC as amended.
Date of completion of procedure	02/05/2007
Target species	Horses
Indication for use	Broad spectrum antiparasitic
ATCvet code	QP54AA01
Concerned Member States	BE, DE, DK, FR, LU, NL, SK, UK

PUBLIC ASSESSMENT REPORT

The public assessment report reflects the scientific conclusion reached by the HPRA at the end of the evaluation process and provides a summary of the grounds for approval of the marketing authorisation for the specific veterinary medicinal product. It is made available by the HPRA for information to the public, after the deletion of commercially confidential information. The legal basis for its creation and availability is contained in Article 25.4 of EC Directive 2001/82/EC as amended by Directive 2004/28/EC for veterinary medicinal products. It is a concise document which highlights the main parts of the documentation submitted by the applicant and the scientific evaluation carried out by the HPRA leading to the approval of the product for marketing in Ireland.

The Summary of Product Characteristics (SPC) for this product is available on the HPRA's website.

I. SCIENTIFIC OVERVIEW

The quality / safety / efficacy aspects of this product are identical to Animec 18.7 mg/g Oral Paste for Horses (IE/V/0204/001/MR).

II. QUALITY ASPECTS

See section I.

IV. CLINICAL ASSESSMENT

See section I.

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V. OVERALL CONCLUSION AND BENEFIT/RISK ASSESSMENT

The quality / safety / efficacy aspects of this product are identical to Animec 18.7 mg/g Oral Paste for Horses (IE/V/0204/001/MR).
The data submitted in the dossier for Animec 18.7 mg/g Oral Paste for Horses (IE/V/0204/001/MR) demonstrate that the quality of the product is acceptable and that, when the product is used in accordance with the Summary of Product Characteristics, the risk benefit profile for the target species is favourable. In addition, the product does not pose an unacceptable risk to users or the environment.

VI. POST-AUTHORISATION ASSESSMENTS

The SPC and package leaflet may be updated to include new information on the quality, safety and efficacy of the veterinary medicinal product. The current SPC is available on the HPRA website.

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